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| EXAMINER | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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**Continuation of 11.** The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

With regard to the priority issue, as it pertains to Claims 1, 2, 4, 7-12, and 14, Applicant asserts, on page 4 of the response, that the priority documents do provide adequate support for the amended claims under 35 U.S.C. 119(e) and 120. Applicant further states that each of the independent claims have been amended to recite a vector encoding an NMDAR-1 antigen, subject matter that the Office action acknowledges is fully supported and enabled by the priority documents. Contrary to Applicant's assertion, the Office action does not acknowledge that the methods and compositions, as presently claimed, are enabled. Given that the enablement rejection is being maintained, the priority issue also remains. The earlier-filed applications fail to provide an enabling disclosure for the invention now being claimed in Claims 1, 2, and 7-12 for the same reasons applied to the instant application in the rejection under 35 U.S.C. 112, first paragraph.

The priority issue pertaining to Claims 4 and 14 is **withdrawn** in view of the cancellation of these claims. The priority issue is maintained for Claims 1, 2, and 7-12.

With regard to the rejection of Claims 1, 2, 4, 7-12, and 14 under 35 U.S.C. 112, first paragraph, Applicant notes, at page 5 of the response, that the "whereby" clause of Claim 12 has been amended to specify that the method ameliorates epilepsy or stroke in a subject. However, neither Claim 11 nor 12 recite that the vector is given via oral administration prior to the neuronal insult.

At page 5 of the response, Applicant alleges that the specification enables the use of vectors other than AAV because several alternative vectors and methods of delivery are listed in section IV "Delivery Systems" of the specification. However, giving due consideration to all the *Wands* factors, including but not limited to, the unpredictability in the art of DNA vaccination, it is maintained that the specification

fails to enable the use of vectors other than AAV. See especially the evidence cited and discussed at pages 6-11 of the Office action of 11/21/05, which details the difficulties intrinsic to designing appropriate vectors for genetic immunization protocols sufficient to produce a therapeutic effect.

At page 5 of the response, Applicant asserts that they disagree with the suggestion that the claims are enabled only for the treatment of rats. Applicant further asserts that the working examples do not represent the only enabled embodiment and that it is improper to read limitations contained in the specification into the claims. With regard to the rats exemplified, Applicant alleges, at page 6 of the response, that they are animal models accepted by those skilled in the art. Applicant points to MPEP 2164.02 for stating that an animal model constitutes a working example if that example correlates with a disclosed or claimed method invention. However, given the teachings of McCluskie et al. (see the Office action of 11/21/05 at page 10), the results obtained in a rat model of genetic immunization does not correlate with results obtained with other species. Specifically, McCluskie et al. teaches that the strength and nature of the immune responses to administration of DNA vaccines varies between species and that it is not clear that the results from one species are predictive in another (page 287, abstract).

The rejection of Claims 4 and 14 under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure for the full scope, is **withdrawn** in view of the cancellation of these claims.

Therefore, Claims 1, 2, and 7-12 remain rejected under 35 U.S.C. 112, first paragraph, for reasons of record.

With regard to the rejection of Claims 1, 2, 4, 7, 8, and 10 under 35 U.S.C. 103(a), Applicant asserts, at page 6 of the response, that Lissin describes increasing expression of NMDA receptors in hippocampal neurons using adenoviral expression to increase the number of receptors and their signal transduction activity. Applicants contend that nowhere in Lissin is there any suggestion that inhibiting

NMDA receptor activity can have a therapeutic effect. Given that the claims under rejection are composition claims, Lissin need not teach or suggest that inhibiting NMDA receptor activity can have a therapeutic effect. In fact, Lissin need not teach inhibiting NMDA receptor activity at all, given that the disclosed compositions are suitable for that purpose. Lissin teaches the composition itself and nothing more is required. When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent. See MPEP 2112.01 and *In re Best,* 195 USPQ 430, 433 (CCPA 1997). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989). In the instant case, there is no evidence demonstrating that the claimed products are functionally different than those taught by the prior art.

At page 6, paragraph 4 of the response, Applicant asserts that Lissin's focus is to increase NMDA activity as a method of elucidating NMDA receptor signaling from other receptors found in neuronal synapses, effectively teaching away from a composition that would elicit production of NMDA receptor-1 antibodies for inhibiting NMDA activity. As noted in the rejection of record, Lissin explicitly teaches an adenovirus encoding the NMDA receptor NR1 (abstract; page 7098, column 1, paragraphs 2-3; and Figure 1). Therefore, the reference teaches all the limitations of the claims as written, with the exception of the pharmaceutical carrier. In Claim 8, Applicant explicitly claims an adenovirus vector. Thus, it is unclear why the adenovirus vector of Lissin would not be suitable for eliciting production of NMDA receptor-1 antibodies. There is no evidence on the record demonstrating that such a composition would

not be "capable of being expressed in a subject to elicit production of NMDA receptor-1 antibodies that inhibit NMDA activity" as set forth in Claim 1. Applicants are reminded that Attorney argument cannot take the place of actual evidence. See MPEP § 2145 and 716.01(c)(II). The arguments of counsel cannot take the place of evidence in the record. *In re Schulze* 145 USPQ 716, 718 (CCPA 1965). Lissin need not teach inhibiting NMDA activity because the claims are directed to the compositions and Lissin teaches the compositions. Nothing more is required. The adenoviral vector of Lissin is identical to the vector recited in the claims.

At page 6, paragraph 5 of the response, Applicant alleges that "the composition of Lissin is not the same as the composition of claim 1 since Lissin's composition does not comprise a nucleic acid sequence *encoding for an NMDAR-1 antigen* to elicit *production of NMDA receptor-1 antibodies* that *inhibit NMDA activity*" (emphasis original). Applicant further alleges, at page 7 of the response, that the Examiner's argument is essentially an inherency argument and the Office action fails to demonstrate that Lissin's compositions would necessarily function for a purpose (antibody production) that is not at all suggested or taught. However, as noted in the prior Office actions of 11/21/05 (pages 12-13), 11/30/06 (page 11), 1/4/08 (page 15), 12/17/08 (page 8), and 6/11/09 (page 8), in the absence of evidence to the contrary, the burden is upon the Applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989). In the instant case, there is no evidence demonstrating that the claimed products are functionally different than those taught by the prior art.

At page 7 of the response, Applicant asserts that the combination with Kammescheidt does not overcome the deficiencies of Lissin since there are still no teachings or suggestions of "a composition to

*elicit production of NMDA receptor-1 antibodies* that *inhibit NMDA activity*" (emphasis original). This argument has already been addressed hereinabove and in the prior Office actions.

The rejection of Claim 4 under 35 U.S.C. 103(a), as being unpatentable over Lissin et al. (1998) in view of Kammescheidt et al. (1996), is **withdrawn** in view of the cancellation of this claim.

Therefore, Claims 1, 2, 7, 8, and 10 remain rejected under 35 U.S.C. 103(a), for reasons of record.

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.